JUN 2 4 2004

K033303
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Spine Wave, Inc.

Two Enterprise Drive
Suite 302
Shelton, CT 06484

Phone: 203-944-9494
Fax: 203-944-9493

510(k) Summary
The Wafer System™

I. Submitter Information:

Submitter's Name: Spine Wave, Inc.
Two Enterprise Drive
Suite 302
Shelton, CT 06484
Telephone: 203-944-9494
Telefax: 203-944-9493

Contact: Ronald K. Smith
Date Prepared: October 13, 2003

II. Device Information

Trade name: The Wafer System
Common name: Wedge Osteotomy Spacer
Classification name: Plate, Fixation, Bone

III. Device Description

The Wafer System consists of a delivery gun, a delivery track and a wafer cartridge assembly. The Wafers are used to open the osteotomy and act as a spacer until bone graft and supplemental fixation can be placed.

The Wafer System Implants are manufactured from Polyetheretherketone (PEEK) with 6% Barium Sulfate.

IV. Intended Use

The Wafer System, in conjunction with commercially available supplemental fixation, is intended for use in proximal tibial opening wedge osteotomies as a means to restore anatomical alignment and relative position.

V. Substantial Equivalence

The Wafer System was demonstrated to be substantially equivalent to the Arthrex Opening Wedge Osteotomy System (K973812) and the Synthes Spiked Washer (K011583). In addition, mechanical testing demonstrated that The Wafer System met the performance requirements for its intended use. Dissimilarities between The Wafer System and the predicate devices do not affect the safety or effectiveness of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2004

Ronald K. Smith
Spine Wave, Inc.
Two Enterprise Drive, Suite 302
Shelton, Connecticut 06484

Re: K033303
Trade/Device Name: The Wafer System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: March 25, 2004
Received: March 26, 2004

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033303

Device Name: The Wafer System

Indications For Use:

The Wafer System, in conjunction with commercially available supplemental fixation, is intended for use in proximal tibial opening wedge osteotomies as a means to restore anatomical alignment and relative position.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restor...
and Neurological Devices

510(k) Number K033303

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)